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Editorial

The Era of Publication Ethics

In South Korea, the Bioethics and Safety Act initially enforced in 2005 was revised in February 2013. Therefore, the Editorial Board of the *Korean Journal of Urology* (KJU) will enforce the research and publication ethics rules for submitted manuscripts. Accordingly, research on human subjects must pass Institutional Review Board (IRB) approval. According to the act, if the article does not meet one of the criteria for exemption, then the authors must describe the decision of the IRB when submitting a paper. Based on the law of domestic regulations, clinical trials conducted since 2001, when clinical trial management standards took effect, should describe the approval and other human subjects research conducted since 2 February 2013 with the revision and enforcement of the Bioethics and Safety Act should do the same. At the acceptance stage, KJU editors will also ask authors to submit a copy of the IRB approval or the IRB approval number. The editors have a duty to validate the IRB approval.

A clinical trials registry is a critical issue. The final objective of a clinical trials registry is to increase the transparency of research to the public and access to clinical trials [1]. The first online registry for clinical trials was ClinicalTrials.Gov, which is managed by the US National Library of Medicine and is the online registry most widely used nowadays. It is hoped that clinical trials registries may decrease selective reporting bias [2]. Editors are to take measures to address false IRB registry. First, the KJU needs to establish regulations. Accordingly, the Editors will issue a warning to authors and restrict submission for a certain period. If the ethical problem is considered critical, severe disciplinary actions including withdrawal of papers or notice to the director of the author's affiliation will be imposed.

Another important point concerning IRB approval is that of obtaining consent from subjects. Authors and editors are obligated to confirm that all medical research involving human beings complies with the Helsinki declaration and the Bioethics and Safety Act. Clinical trials on medicine and medical appliances, which are regulated by the pharmaceutical law and medical appliances act, are not exempted from IRB deliberation. Also, clinical trials collecting and recording personally identifiable information are not exempted from IRB deliberation. If the risk of the trial is minimal, the trials may be exempted from IRB deliberation.

Complying with fastidious regulations may not be easy. However, abidance with these global regulations will greatly contribute to internationalization of the KJU.

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